NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects of ofatumumab on the immune response to flu vaccine in people with multiple sclerosis

Thank you!

Thank you to the participants who took part in the clinical trial for multiple sclerosis. Every participant helped the researchers learn more about the trial drug **ofatumumab** also known as **OMB157**.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: COMB157GUS12

Drug studied: Ofatumumab also known as OMB157

Sponsor: Novartis

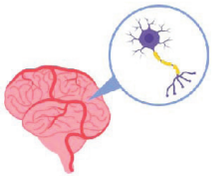
If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial. Other clinical trials may have different findings.

What was the main purpose of this trial?

The purpose of this trial was to find out if people with **multiple sclerosis (MS)** who were treated with **ofatumumab** could produce an **immune response** to flu vaccine.

An **immune response** is how the body identifies and protects itself from bacteria, viruses, and other harmful substances.



Multiple sclerosis (MS) is a condition that affects the brain and spinal cord. In people with **MS**, the protective coating around the nerves, called **myelin**, gets damaged. This leads to nerve damage and scar tissue formation, causing various symptoms. Symptoms of **MS** can include tiredness, difficulty walking, numbness or tingling, muscle weakness, vision problems, and problems with coordination and balance.

Treatments used for **MS** can impact the immune system, which may reduce the effectiveness of vaccines.

Ofatumumab is an approved treatment for **relapsing MS**. In people with **MS**, certain types of white blood cells can cause damage to the nervous system and lead to **MS** symptoms. **Ofatumumab** works to reduce the number of these white blood cells in the nervous system.

People with **relapsing MS** have new symptoms of **MS** after a period of improvement.

Since white blood cells protect the body against germs, people treated with **ofatumumab** might have a higher risk of getting flu or having worse outcomes with the flu.

In this trial, researchers wanted to find out if people with **relapsing MS** who are treated with **ofatumumab** were able to produce an immune response to the **flu vaccine**.

Trial drug
Ofatumumab
pronounced as
OH-fa-TOO-moo-mab

The **flu vaccine** protects against various types of influenza viruses. Among them, types A and B cause flu, are very easy to catch, and have similar symptoms. These viruses are further divided into strains and are named based on their type, the species they come from, and the place where they were first found.

To learn more about the immune response to **flu vaccine**, researchers compared the effects of **ofatumumab** to other MS treatments.

Other MS treatments included drugs (interferon and glatiramer acetate) that were collectively called injectable diseasemodifying therapy which, unlike **ofatumumab**, were not expected to affect the body's immune response to vaccines.

The trial purpose was to answer these main questions:

- How many participants treated with ofatumumab showed an immune response to the flu vaccine at least 4 weeks after vaccination?
- What adverse events did the participants have during this trial?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial. It **may** or **may not** be caused by treatments in the trial.

How long was this trial?

The trial began in January 2021 and ended in July 2023. An individual participant could be in the trial for a total duration of up to 8 months.

The researchers completed this trial as planned. When the trial ended, the researchers collected information from participants and created a report of the trial results. This summary is based on that report.

Who was in this trial?

63 participants with **multiple sclerosis (MS)** from the United States joined this trial.

Participants' ages ranged from 22 to 54 years. Their average age was about 41 years.

The number of participants by gender and race is shown below.

Gender

15 **Men**	48 **Women**

Race

9 **Black** or **African American**	54 **White**

The participants could take part in this trial if they were:

- between 18 and 55 years of age
- diagnosed with **relapsing multiple sclerosis (MS)**
- planning to start **ofatumumab** or had already been receiving **ofatumumab** for at least 2 weeks before the start of this trial
- willing to receive a flu vaccine

What treatments did the participants receive?

Participants received either of the following treatments:

OMB157 20 milligrams (mg) given as an injection under the skin.

Other MS treatments, interferon or glatiramer acetate, given as an injection under the skin or into a muscle.

In addition, all the participants received the **flu vaccine** as an injection into a muscle.

In this trial, the participants, trial doctors, and trial staff knew what treatment each participant received.

What happened during this trial?

Before treatment — Up to 1 week

Trial doctors checked the participants' health to ensure they could take part in this clinical trial.

During treatment — Up to 7 months

63 participants joined the trial. This trial had 2 parts: **Part 1** and **Part 2**

Part 1 (1 month): Participants were divided into one of the following 3 groups:

	Flu vaccine	Treatment
Group 1 22 participants	Within 9 days after the initial assessment visit.	Received 20 mg **ofatumumab** at Weeks 2, 3, and 4.
Group 2 22 participants	Within 9 days after the initial assessment visit.	Continued receiving **ofatumumab** as prescribed by their doctors.
Group 3 19 participants	Within 9 days after the initial assessment visit.	Continued receiving **other MS treatments** as prescribed by their doctors.

Part 2 (6 months): Participants in Group 1 and Group 2 who completed **Part 1** of the trial could enter Part 2 of the trial and continue the treatment.

After treatment — Up to 1 month

Participants were contacted by researchers or returned to their trial site within 7 days of receiving their last treatment for follow-up.

What was the main result of this trial?

The majority of the participants showed an immune response to the flu vaccine at least 4 weeks after vaccination. The immune responses varied depending on the influenza strain.

How many participants treated with ofatumumab showed an immune response to the flu vaccine at least 4 weeks after vaccination?

To answer this question, researchers collected blood samples from participants and checked whether they had antibodies against different strains of the influenza virus that was used as a vaccine.

The results below show the immune response towards various types of influenza A and B strains.

Note: The **influenza** virus types **A** and **B** are divided into strains and are named based on their type, the species they come from, and the place where they were first found.

Number (percentage) of participants who showed an immune response at least 4 weeks after receiving the flu vaccine during this trial

	Group 1 (18 participants) started **ofatumumab** 20 mg in this trial	**Group 2** (22 participants) continued on **ofatumumab**	**Group 3** (17 participants) previously on other MS **treatments**
Influenza A **Brisbane**	**5 of 5** 100%	**2 of 2** 100%	**1 of 1** 100%
Influenza A **Cambodia**	**13 of 13** 100%	**4 of 5** 80%	**6 of 7** 86%
Influenza A **Kansas**	**5 of 5** 100%	**2 of 2** 100%	**1 of 1** 100%
Influenza A **Michigan**	**5 of 5** 100%	**2 of 2** 100%	**1 of 1** 100%
Influenza A **Singapore**	**5 of 5** 100%	**2 of 2** 100%	**1 of 1** 100%
Influenza A **Victoria**	**13 of 13** 100%	**5 of 5** 100%	**7 of 7** 100%

	Group 1 (18 participants) started **ofatumumab** 20 mg in this trial	Group 2 (22 participants) continued on **ofatumumab**	Group 3 (17 participants) previously on other MS **treatments**
Influenza A **Wisconsin**	**8 of 13** 62%	**8 of 20** 40%	**11 of 16** 69%
Influenza B **Colorado**	**3 of 5** 60%	**1 of 2** 50%	**1 of 1** 100%
Influenza B **Phuket**	**14 of 18** 78%	**15 of 22** 68%	**13 of 17** 76%
Influenza B **Washington**	**10 of 13** 77%	**1 of 5** 20%	**5 of 7** 71%

What adverse events did the participants have?

Trial doctors keep track of all **adverse events** that happen in trials, even if they think the adverse events are not related to the trial treatments.

Many trials are needed to know if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the start of treatment up to 1 month after the last dose of trial treatment.

An **adverse event** is:

- any **sign or symptom** that the participants have during a trial
- considered **serious** when it is lifethreatening, causes lasting problems, the participant needs hospital care, or results in death

Adverse events **may** or **may not** be caused by treatments in the trial.

24 out of the 63 participants had adverse events. 1 participant had an adverse event that was considered serious. The researchers concluded that there were no new safety concerns for **ofatumumab** for this trial.

How many participants had adverse events?

Participants who:	**Group 1** (22 participants)	**Group 2** (22 participants)	**Group 3** (19 participants)
Had at least 1 serious adverse event	**0**	**1 of 22** 5%	**0**
Had at least 1 other adverse event	**16 of 22** 73%	**6 of 22** 27%	**2 of 19** 11%

What serious adverse events did the participants have?

One participant in **Group 2** had an adverse event that was considered serious. It was **a temporary worsening of multiple sclerosis** (multiple sclerosis pseudo relapse).

What other adverse events did the participants have?

24 participants had other adverse events. The table below shows the other adverse events that happened in **9% or more** of participants in any group.

	Group 1 (22 participants)	Group 2 (22 participants)	Group 3 (19 participants)
Reaction related to the injection site Injection related reaction	**4 of 22** 18%	**0**	**0**
Headache	**3 of 22** 14%	**1 of 22** 5%	**0**
Feeling sick Nausea	**3 of 22** 14%	**0**	**0**
Pain	**3 of 22** 14%	**0**	**0**
COVID-19 infection	**2 of 22** 9%	**0**	**1 of 19** 5%
Fever Pyrexia	**2 of 22** 9%	**0**	**1 of 19** 5%
Flu-like illness Influenza-like illness	**2 of 22** 9%	**1 of 22** 5%	**0**
Shivering Chills	**2 of 22** 9%	**0**	**0**
Tiredness Fatigue	**2 of 22** 9%	**0**	**0**
Urinary tract infection (UTI)	**2 of 22** 9%	**0**	**0**
Muscle cramps Muscle spasms	**1 of 22** 5%	**2 of 22** 9%	**0**

What was learned from this trial?

Researchers learned about the immune response to the flu vaccine in the participants with **multiple sclerosis** (**MS**) who were treated with **ofatumumab**.

The researchers concluded that:

- Most of the participants showed an immune response to flu vaccine at least 4 weeks after vaccination. The immune responses varied depending on the influenza strain.
- There were no new safety concerns about **ofatumumab** from this trial.

The findings from this trial may be useful in understanding the benefits and risks associated with **ofatumumab** and the flu vaccine.

At the time of writing this summary, other trials with **ofatumumab** were ongoing.

Where can I learn more about this trial?

Follow these steps to find the scientific summary:

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website, **www.novctrd.com**.

For more information about this trial, go to the following website:

- **www.clinicaltrials.gov** search using the number **NCT04667117**

If more trials are planned, they will appear on the public websites above. When there, search for ofatumumab, influenza A vaccine, or influenza B vaccine.

Full clinical trial title: An open-label multicenter study to assess response to influenza vaccine in participants with multiple sclerosis treated with ofatumumab 20 mg subcutaneously

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